

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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CHEMBIO DIAGNOSTIC SYSTEMS, INC.,

Plaintiff,

MEMORANDUM OPINION
AND ORDER

-against-

CV 04-1149 (JS) (ETB)

SALIVA DIAGNOSTIC SYSTEMS, INC.,

Defendant.
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Before the Court are two motions: (1) one by defendant Saliva Diagnostic Systems, Inc. (“Saliva Diagnostic Systems” or “SDS” or “defendant”), for an order compelling the plaintiff to produce certain documents and (2) a cross-motion by plaintiff, Chembio Diagnostic Systems, Inc. (“Chembio” or “plaintiff”) for a protective order pursuant to Rule 26(c). Defendant SDS also seeks sanctions in the form of costs and fees incurred in pursuing its motion to compel. The substance of the motions significantly overlap.

I. BACKGROUND

A. The Disputed Discovery

Plaintiff, Chembio, and defendant, SDS, are competitors in the field of rapid, on-site testing for HIV and other infectious diseases. (Declaration of Lawrence Siebert, CEO and President of Chembio Diagnostics, Inc. (“Siebert Decl.”) ¶23.) Chembio sells rapid diagnostic test kits for various infectious diseases, including a rapid test for HIV sold under the trademark “Sure Check HIV.” (Siebert Decl. ¶ 4.) The Sure Check HIV device is a single-use, self-contained closed system for the collection, processing and analysis of a blood sample for the detection of HIV antibodies. (Id. ¶ 7.) Sure Check HIV is one of Chembio’s two HIV tests that

are now pending FDA approval. (Mem. in Supp. of Pl.’s Mot. for a Protective Order under Rule 26(c) (“Pl.’s Mem.”) at 2.) The defendant, SDS, sells a product called the “Saliva Hema-Strip” (the “Hema-Strip device”). (Declaration of Mo Bodner, COO of SDS, in Response to the Rule 56.1 Statement of Chembio Diagnostic Systems (“Bodner Decl.”), Annexed to Kaplan Decl. as Exh. E, ¶ 2.) Defendant claims that the plaintiff’s device is an exact copy of SDS’s Saliva Hema-Strip. (*Id.*) For a period of time that concluded in early 2003, Chembio and SDS had a business relationship that involved SDS’s Hema-Strip. (Declaration of Leo Ehrlich, CFO of SDS (“Ehrlich Decl.”) ¶ 2.) The relationship terminated in the first half of 2003, and Chembio and SDS are now competitors. (Siebert Decl. ¶ 23.)

On March 18, 2004, Chembio filed the complaint herein seeking declaratory judgment that the plaintiff’s Sure Check HIV barrel device did not infringe the defendant’s U.S. Patent No. 5,935,864 (“‘864 patent”), or in the alternative, that the ‘864 patent is invalid or unenforceable. (Pl.’s Complaint at 5-6.) SDS has filed counterclaims for the infringement of the ‘864 patent. (Def.’s Answer and Counterclaim.) The ‘864 patent, which through assignment is enforceable by SDS, describes a device which obtains a liquid specimen. (‘864 Patent, annexed to Pl.’s Mot. as Exh. D.) The ‘864 patent is discussed in further detail infra, Part B.

In November 2004, defendant SDS propounded its first set of interrogatories and first set of document requests to plaintiff Chembio. (Defendant Saliva Diagnostic System Inc.’s First Set of Interrogatories and First Set of Document Requests to Plaintiff Chembio Diagnostic Systems, Inc. (“Def.’s First Set of Interrogatories and Document Requests”), dated November 10, 2004.)

In late December 2004, plaintiff responded, objecting to many of the defendant's requests on the ground that they are not relevant to a claim or defense in this action, and that they constitute protected trade secrets. (See Pl.'s Objections and Responses to Defendant's First Set of Interrogatories and Document Requests ("Pl.'s Objections and Responses"), annexed to Def.'s Mot. to Compel as Exh. C. See also Pl.'s Opp'n at 2; Siebert Decl. ¶¶ 32-35.)

On January 26, 2006, the Court approved a Stipulation and Order Governing the Protection and Exchange of Confidential Material, signed by both parties. (See Order by the undersigned, dated January 24, 2006.) The stipulation provides that certain highly sensitive information may be designated by the producing party as "Highly Confidential– Counsel Only," which may only be disclosed to counsel of record for the parties and members or staff of the firm, outside consultants or experts not objected to by the producing party, the Court, and outside services companies or jury consulting services. (Stipulation and Order Governing the Protection and Exchange of Confidential Material at 3, 6-7, annexed to Decl. of Jeffrey Kaplan as Exh. F.)

On February 13, 2006, defendant filed its letter motion to compel, seeking responses to its document requests, and arguing that SDS permitted Chembio unfettered access to all requested, non-privileged documents, and produced the same categories of documents that Chembio now refuses to produce. (Letter Motion from Jeffrey I. Kaplan to the undersigned ("Def.'s Mot. to Compel"), dated February 13, 2006, at 1.) Defendant argues that Chembio repeatedly led defendant to believe that the documents would be produced, and that it was not until the defendant's copy service arrived at Chembio's offices for the documents that defendant

was informed that Chembio had retained new counsel, Daniel Burke (“Burke”), and that Burke objected to the reciprocal production of documents.¹ (Id. at 2.) The categories of documents which defendant seeks to compel, and for which plaintiff seeks a protective order, can be categorized primarily as concerning either “infringement discovery” or “damages discovery.” The parties summarized the requests as follows: (1) all FDA files, including trials and evaluations, concerning the Hema Strip and Sure Check HIV products; (2) documents relating to the production of the Hema Strip/Sure Check HIV product; (3) summaries of FDA trials and evaluations and advertising, packaging, etc. for the two products; (4) and research and development (“R&D”) relating to the Hema Strip/Sure Check HIV product (together, the “infringement discovery”); and (5) documents relating to distributors and/or sales representatives for the two products, as well as invoices and customer summaries; and (7) product cost

¹Burke also objected to the method by which the parties had been exchanging documents. Prior to Burke’s appearance on the case, documents were provided to opposing counsel, copied, reviewed by opposing counsel, and then reviewed by the producing parties’ counsel for final approval. Burke states that this arrangement resulted in plaintiff being provided with copies of SDS documents that were not yet “formally produced.” Both parties acknowledged at oral argument that SDS produced its counterparts to documents Chembio seeks to withhold (e.g., documents SDS submitted to the FDA), but SDS asked plaintiff not to review the documents pending the outcome of the cross-motions at issue herein. (See Letter from Jeffrey I. Kaplan to Daniel P. Burke, dated February 14, 2006, stating with regard to documents related to SDS’s FDA submissions, “Chembio has taken the position in this litigation that such documents are not discoverable. While SDS strongly disagrees, the Court has yet to rule. I’m sure you will concur that it is highly inappropriate for Chembio to refuse to produce FDA documents on the grounds that they are very competitively sensitive, while at the same time, insisting that SDS produce such documents to Chembio. Accordingly, we request that with respect to the foregoing designated documents, you withhold review of them until the court rules on the motion to compel.”). In a reply letter from Burke to Kaplan dated February 17, 2006, Burke stated that plaintiff agreed to honor defendant’s request not to review the documents until the court ruled on the pending motions. (Letter from Daniel P. Burke to Jeffrey I. Kaplan dated February 17, 2006, annexed to Burke Decl. at Exh. E.)

Defendant does not rely on the stipulation of reciprocal discovery for purposes of this motion. Accordingly, it is not relied on by the Court.

documents (together, the “damages discovery”). (Def.’s Letter Mot. to Compel, Exh. D.)

Defendant argues that the infringement discovery is relevant to its infringement counterclaim because the sought-after discovery goes directly to the operation of the Chembio device, the results of testing it, and how it performs. (Def.’s Letter Mot. to Compel at 2.) Defendant argues in particular that it seeks the testing data Chembio provided to the FDA because SDS believes this testing data will contradict the results of the testing data that Chembio has produced from testing conducted specifically for this litigation. (Id. at 3.)

The plaintiff objects to the production of the infringement discovery documents on the ground that they are not relevant to a claim or defense in this action, and that they constitute protected trade secrets. (Pl.’s Opp’n at 2.; Siebert Decl. ¶¶ 32-35.) Plaintiff states: “[u]nlike the documents already produced, the remaining Chembio FDA related documents, detailed manufacturing protocols, correspondence with vendors, and manufacturing costs information” are not relevant to a claim or defense in this action. (Pl.’s Opp’n at 2.)

On February 24, 2006, Chembio filed its motion for a protective order. Chembio specifically objects to producing and requests a protective order that disclosure or discovery not be had relating to: (1) Chembio’s application for premarketing approval now pending before the U.S. Federal and Drug Administration, including supporting information, evaluations and clinical trials, except to the extent it is directly related to documents already photocopied and provided to SDS’s counsel; (2) all chemistry and details relating to Chembio’s test strip; (3) Chembio’s manufacturing protocols; (4) Chembio’s manufacturing costs; and (5) Chembio’s vendors, including communications between Chembio and its vendors. (Memorandum in

Support of Plaintiff's Motion for a Protective Order Under Rule 26(c) ("Pl.'s Mem. in Supp."), at 1, 10.) Chembio claims that it has produced to SDS the discovery relevant to this case, including: (1) all of Chembio's sales of its Sure Check HIV test kit; (2) specifications, engineering drawings, testing and experiments for Chembio's accused Sure Check HIV plastic sampler, its lower filter and its upper filter; (3) all advertising; (4) all packaging and inserts; (5) documents relating to experiments conducted with and without the filters; (6) actual product samples, and (7) manufacturing and quality control documents which had been submitted to the FDA relating to the positioning of Chembio's filters during the manufacture and the inspections to perform proper placement. (Id. at 11.)

B. The '864 Patent

Plaintiff Chembio seeks a declaratory judgment that the '864 patent is not infringed by Chembio's Sure Check HIV device, or in the alternative, that the '864 patent is invalid or unenforceable. SDS has counterclaimed for patent infringement. Because the present discovery dispute concerns issues of relevance, some discussion of the '864 patent is appropriate.

1. The Method by which the Fluid Sample is Drawn into the Device Barrel

The '864 patent describes a sample kit and method for collecting a sample of liquid, such as blood, for analytical testing within a testing chamber. (Saliva Diagnostic System Inc.'s Response to Chembio's Motion for Protective Order under Rule 26 and in Further Support of SDS' Request for Costs and Fees ("Def.'s Response to Pl.'s Mot. for Protective Order"), at 2; see also '864 Patent, annexed to Pl.'s Mot. as Exh. D.) The '864 Patent protects both a method and a device: Claim 1 of the '864 patent describes a method, and Claim 6 of the '864 Patent describes a device. (See '864 Patent.) Claim 1 protects a "method for collecting a sample of

liquid specimen for analytical testing consisting essentially of the steps of” (‘864 Patent, Col. 1 (emphasis added).) The language “consisting essentially of” is a term of art in patent law, and, as defendant states, forms the cornerstone of the parties’ infringement dispute. (Def.’s Response to Pl.’s Mot. for Protective Order at 4.) The term has been interpreted to permit the inclusion of components not listed in the claim, provided they do not “materially affect the basic and novel properties of the invention.” Dow Chemical Co. v. American Cyanamid Co., 615 F.Supp. 471, 484 (E.D.La.1985), aff’d, 816 F.2d 617 (Fed.Cir.), cert. denied, 484 U.S. 849, 108 S.Ct. 149, 98 L.Ed.2d 105 (1987). As defendant notes, “[p]ut another way, if the allegedly infringing device includes extra components not recited in the claims, those extra components may or may not take the device outside the scope of the claim, depending upon whether such extra components ‘materially affect the basic and novel properties of the invention.’” (Def.’s Response to Pl.’s Mot. for Protective Order at 4.)

Here, the “extra components” at issue are the upper and lower “frits” which plaintiff Chembio has included in its device, arguing that the frits are additional elements that “materially affect the basic and novel properties of the invention,” such that the frits take the Chembio device outside of the scope of the “consisting essentially of” claim language of SDS’ ‘864 patent.

Chembio’s Vice-President of Research and Development, Javan Esfandiari (“Esfandiari”), states in his declaration that Chembio’s device does not function properly without the lower filter. (Declaration of Javan Esfandiari (“Esfandiari Decl.”) ¶ 18.) As Esfandiari explains, “[w]ithout the lower filter, when the tip of Chembio’s Sure Check HIV Barrel Device is inserted into the vial containing the buffer solution, the mixture of the sample and the solution splashes through

the barrel of the device. . . Due to the splashing, the mixture of the sample and the solution is not properly absorbed onto the test strip.” (Esfandiari Decl. ¶¶ 19-20, 27-29.)

Defendant, on the other hand, argues that the novelty of the device protected by the ‘864 patent is that the fluid sample collected by the device is drawn into the tube of the device by capillary action (the scientific principle describing the inherent surface tension between the inside of the capillary end of the device and the fluid to be collection). (Def.’s Response to Pl.’s Mot. for Protective Order at 3.) This design is such that “[n]o absorptive material is required to acquire the blood sample into the capillary tube [], because the dimensions are such that the capillary force is sufficient on its own.” (*Id.*) In support of its position, defendant submitted the affidavit of Maura Crossen (“Crossen”), a research technologist at American Bio Medica Corporation, which manufactures an HIV testing device of the type described by patent ‘864. (Declaration of Maura Crossen (“Crossen Decl.”) ¶¶ 1-2.) Crossen states that she conducted experiments with the device with the lower frit removed, and determined that the device works accurately with the frit removed. (*Id.* ¶¶ 5-8.) Crossen states that the “frit serves to prevent splashing of sample and reagent, however, the device works even though splashing occurs.” (*Id.* ¶ 8.) Thus, defendant is prepared to contend that, contrary to plaintiff’s representations, the device works without the frits. (Def.’s Response to Pl.’s Mot. for Protective Order at 5.) Defendant argues that the improvement represented by the frits merely controls the flow rate, but do not “materially affect the basic and novel properties of the invention” to such a degree that Chembio’s device is removed from the scope of SDS’ ‘864 patent. (*Id.*) The degree of absorbency of the lower frit is also disputed: if the lower frit merely passes the fluid sample substantially untouched, the presence of the frit does not “materially affect the basic and novel

properties of the invention,”² and therefore, the Chembio device might be deemed infringing; if, on the other hand, the lower frit is highly absorbent, Chembio would contend that the presence of the frit does “materially affect the basic and novel properties of the invention,” such that Chembio’s device is removed from the scope of SDS’ ‘864 Patent. (Id.)

The function of the frits was at issue on the parties’ cross-motions for summary judgment, denied by Memorandum and Order of Judge Seybert dated September 27, 2005. (Memorandum and Order by Judge Seybert, dated September 27, 2005 (“Judge Seybert opinion”). In the opinion, Judge Seybert notes that

[t]he following facts are disputed: (1) whether the lower filter absorbs any of the sample when the buffering solution is forced through the opening, (2) the function of the lower filter when the mixture of the solution and sample is within the container, (3) the upper filter’s interaction with the sample, and (4) the functionality of the device without the lower filter in place.” (Judge Seybert opinion at 9.) In her opinion, Judge Seybert further stated that the “parties are in disagreement as to the construction and operation of the allegedly infringing Barrel Device. This issue, however, is not ripe yet for adjudication. . . Since there was no discovery prior to the instant motion being filed, this Court is unable to make any ruling with regard to the device.

Id. at 17-18.

2. The Test Strip

²SDS maintains that the lower frit in Chembio’s device is not absorptive: “[t]he frit placed in the bottom of the test barrel diminishes the splashing of the sample, but it is not designed to absorb any of the sample, and in fact, must be specifically designed to pass the fluid sample through without absorption. . . [t]he frit is intended to be a filter, and to whatever extent it absorbed any of the fluid sample, this sample would diminish the amount available for use by the test strip, and would be counterproductive to the operation of the device. Hence, frit merely gets damp as the fluid to be tested passes through, but no absorptive action occurs.” (Bodner Decl. ¶¶ 3-4.)

Claim 6 of the '864 Patent protects a device— the sample kit. (See '864 Patent.)

The parties agree that the sample kit comprises a sample container with a chamber, a top opening, and a bottom opening. (Def.'s Response to Pl.'s Mot. for Protective Order at 2; Pl.'s Mem. in Supp. at 6.) The parties also agree that in operation, a sample such as blood is obtained through the bottom opening and forced out into the chamber for reaction with the test strip inside of the chamber. (Def.'s Response to Pl.'s Mot. for Protective Order at 2; Pl.'s Mem. in Supp. at 7.)

The parties dispute the significance of the test strip to the patent: defendant states that its infringement proof must include proof that the plaintiff's test strip is equivalent to the test strip disclosed in the patent, and that it therefore needs discovery pertaining to plaintiff's test strip. (Def.'s Response to Pl.'s Mot. for Protective Order at 10.) Defendant further argues that it needs the test strip-related discovery to attempt to refute claims discussing the operation of the test strip in the Esfandiari declaration submitted by plaintiff. (Id. at 11; see also Esfandiari Decl. ¶¶ 16-21, stating that the filters prevent the mixture of the solution and sample from splashing, and that "[d]ue to the splashing, the mixture of the sample and the solution is not properly absorbed onto the test strip," thereby producing invalid results.)

The plaintiff argues, on the other hand, that "[t]he '864 patent is not directed to the chemistry of any particular test strip, but rather states '[t]hese test strips are well known in the prior art.'" (Pl.'s Mem. in Supp. at 7 (quoting the '864 patent).) Chembio argues that, accordingly, the chemistry involved in the manufacture of Chembio's test strip and the manner in which Chembio's Sure Check HIV system is assembled are totally unrelated to SDS's '864 patent, and irrelevant to this action. (Seibert Decl. ¶ 10.) Chembio further argues that it has

conducted years of research and spent millions of dollars developing its product, and the chemistry of the test strip is “highly proprietary, valuable trade secret information,” the disclosure of which would irreparably harm Chembio. Id.

II. DISCUSSION

A. Legal Standard for Obtaining Discovery Protective Order

It is a fundamental principle of law that “[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party. . . .” that is admissible, or “reasonably calculated to lead to the discovery of admissible evidence.” Rule 26(b)(1), Federal Rule of Civil Procedure. “Generally, discovery is only limited ‘when sought in bad faith, to harass or oppress the party subject to it, when it is irrelevant,’ or privileged.” Melendez v. Greiner, No. 01 Civ. 7888, 2003 WL 22434101, at *1 (S.D.N.Y. Oct. 23, 2003) (quoting In re Six Grand Jury Witnesses, 979 F.2d 939, 943 (2d Cir. 1992)).

Further, there is no absolute privilege for trade secrets and similar confidential information; however, Federal Rule of Civil Procedure 26(c)(7) provides that a district court, “for good cause shown,” may order “that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way.” Rule 26(c)(7), Fed. R. Civ. P. To demonstrate good cause under this provision, the party seeking the protective order must show that the information sought is a trade secret or other confidential information, and that the harm caused by its disclosure outweighs the need of the party seeking the disclosure. Bank of New York v. Meridien Biao Bank Tanz, Ltd., 171 F.R.D. 135, 143 (S.D.N.Y. 1997). In determining whether information warrants protection as a Rule 27(c)(7) trade secret, courts have considered the following: (1) the extent to which the

information is known outside the business; (2) the extent to which it is known by employees and others involved in the business; (3) the measures taken to guard the information's secrecy; (4) the value of the information to the business or to its competitors; (5) the amount of time, money, and effort expended in development of the information; and (6) the ease or difficulty or duplicating or properly acquiring the information. See Four Star Capital Corp. v. Nynex Corp., 183 F.R.D. 91, 110 (S.D.N.Y. 1997). If the good cause showing is met, the burden shifts to the party seeking discovery to establish that disclosure of the confidential information is relevant and necessary. Four Star Capital Corp., 183 F.R.D. at 110.

Here, Chembio has demonstrated that the discovery sought by SDS is highly confidential trade secret information, and entitled to some degree protection under Rule 26(c)(7), a fact that SDS does not dispute. Having so found, the burden shifts to SDS to establish that disclosure pursuant to the protective order, rather than no disclosure, is warranted because the confidential information is relevant and necessary. This analysis must be conducted with respect to each category of discovery that SDS seeks to compel and Chembio seeks to protect.

B. Infringement Discovery

1. Discovery Pertaining to Method of Sample Acquisition

SDS seeks discovery regarding Chembio's application for premarket approval, now pending before the FDA. Such an application typically requires the applicant to submit "extensive safety testing data and descriptions of manufacturing methods and materials." Reiter v. Zimmer, Inc., 897 F. Supp. 154, 157 (S.D.N.Y. 1995). SDS argues that this discovery is necessary because it is likely to reveal, inter alia, the porosity of the frits, how the absorptive properties affect fluid sample movement, and how tolerant the test strip is to the force of the

capillary action. (Def.'s Response to Pl.'s Mot. for Protective Order, at 8.) SDS argues that these documents go to the heart of the infringement issue in this case, i.e., "how the device works and whether the frits are absorbent and/or have a material effect on the basic and novel properties of the invention." (Id. at 8-9.) Chembio argues this discovery is trade secret information and irrelevant.

This infringement dispute centers on whether or not Chembio's device includes upper and lower frits, which serve to, inter alia, absorb the sample into the capillary end of the device as well as block some of the force of the capillary action. SDS has satisfactorily demonstrated that discovery concerning the details of the presence or absence of these components, as well as the specifics of how they function, is relevant and necessary to help SDS determine whether or not these elements "materially affect the basic and novel properties of the invention," for the purposes of proving that Chembio's device is infringing.

Courts routinely direct that confidential trade secret information be produced subject to the terms of a confidentiality order, and Chembio has made no effort to demonstrate why the confidentiality order in place is inadequate to protect the confidentiality of this information. See Eagle Comtronics, Inc. v. Arrow Communication Laboratories, Inc., 305 F.3d 1303, 1313-1314 (Fed. Cir. 2002) (approving of district court's entry of a protective order in a patent law case to protect highly confidential trade secret information, and directing the district court to impose sanctions on party who violated the protective order); DDS, Inc. v. Lucas Aerospace Power Transmission Corp., 182 F.R.D. 1, 5 (N.D.N.Y. 1998); Dynamic Microprocessor Assocs. v. EKD Computer Sales, 919 F. Supp. 101, 106 (E.D.N.Y. 1996).

Accordingly, Chembio's motion for a protective order related to Chembio's application

for premarket approval now pending before the FDA is denied. Chembio is directed to produce this discovery pursuant to the terms of the Stipulation and Order governing the exchange of confidential information, signed by both parties and approved by this Court on January 24, 2006.

2. Discovery Pertaining to the Test Strip

The defendant seeks, and plaintiff seeks to protect, “all chemistry and details relating to Chembio’s test strip,” (Pl.’s Mot. in Supp. at 1), including all FDA files, production information, and sales pertaining to the test strip. (Def.’s Mot. to Compel, Exh. D.) SDS seeks discovery related to the test strip because “this test strip is recited in the ‘864 claims as a ‘means therein for analytical testing.’” (Def.’s Response to Pl.’s Mot. for Protective Order, at 8.) SDS argues that this “means plus function” claim requires its infringement proof to include proof that the Chembio test strip is the same or equivalent to the test strips disclosed in its ‘864 patent, and so it must have access to Chembio’s test strip chemistry. (Id.) SDS further argues that this discovery is necessary to refute Chembio’s claims that the device does not work without “splashing” onto the test strip, unless frits are installed in the device. (Id.; see also Def.’s Rule 56.1 Statement, ¶¶ 52-59.)

While Chembio is correct in arguing that the patent does not protect the chemistry of the test strip, and defendant’s counsel acknowledged at oral argument that there is nothing unique about the test strip and that it may not need discovery concerning every aspect of the chemical make-up of plaintiff’s test strip, defendant is persuasive in arguing that discovery concerning the chemistry of the test strip is relevant. Plaintiff’s offer to provide defendant with samples of the test strip is insufficient. See Moore U.S.A., Inc. v. The Standard Register Co., No. 98 CV 485C, 2000 WL 876884, at * 1 (W.D.N.Y. 2000) (“the court finds that [defendant’s] offer to provide

[plaintiff] with a sample of the accused adhesive is insufficient. . . [i]f [defendant] purchased certain ingredients from third-party suppliers and is not familiar with the chemical subparts of those ingredients, then it should give [plaintiff] the names of its suppliers and a description of the products purchased.”). Defendant is entitled to the requested discovery regarding the test strip in order to attempt to refute the statements in the Esfandiari declaration that the test strip doesn’t work properly without the frits, due to splashing. Without the requested test strip-related discovery, the defendant is disadvantaged in the use of its own expert in attempting to refute Esfandiari’s claims. It is undisputed that the sought after discovery is confidential trade secret material, but plaintiff has failed to demonstrate why the protective order in place is insufficient to protect the sensitive nature of the discovery.

Accordingly, Chembio’s motion for a protective order related to Chembio’s test strip is denied. Chembio is directed to produce this discovery pursuant to the terms of the Stipulation and Order governing the exchange of confidential information, signed by both parties and approved by this Court on January 24, 2006.

3. Vendor Communications

Defendant also seeks, and plaintiff seeks to protect, discovery concerning Chembio’s vendors, including communications between Chembio and its vendors. Defendant argues that the vendor communications will shed light on details concerning the manufacturing, materials and specifications concerning plaintiff’s device. (Def.’s Response to Pl.’s Mot. at 12.) In addition, defendant argues that plaintiff has put the vendor communications in issue by submitting selected communications in support of its own non-infringement defense. As attachments to the Esfandiari Declaration, plaintiff submitted selected communications with its

vendors Genpor and Porex. (See Attachments to Esfandiari Decl.)

Defendant argues that the vendor communications may be evidence of plaintiff's willfull copying of defendant's device. (Id.) Leo Ehrlich, CFO of SDS, states in his declaration that after the relationship between plaintiff and defendant broke down, the defendant received a fax from one of its vendors, Engineered Plastics, stating that Engineered Plastics received an order from Chembio for 100,000 units of the "Hema Strip Barrel"—SDS's product made with SDS's mold. (Ehrlich Decl. ¶ 6; see also Purchase Order from Chembip to Engineer Plastics, annexed to Ehrlich Decl. as Exh. 1.) Defendant maintains that communications between plaintiff and other vendors may reveal that Chembio instructed other vendors to ship products designed for and used by SDS. (Def.'s Response to Pl.'s Mot. at 13.) Defendant states that "[t]hese communications will form a central part of SDS' proof of willfulness. . . ." (Id.) Plaintiff argues that "SDS is attempting to twist the test for patent infringement into a comparison between products sold by SDS and products sold by Chembio." (Pl.'s Reply Mem. in Supp. at 5.)

A determination of willfulness is relevant to damages insofar as it may entitle the prevailing party to seek treble damages. Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc., 218 F.R.D. 387, 390 n.3 (S.D.N.Y. 2003) (citing 35 U.S.C. § 284; Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 1429 (Fed.Cir.1988)). The vendor communications, which SDS has persuasively argued may demonstrate that Chembio explicitly requested from SDS's vendors products designed for and used by SDS, are clearly relevant to SDS's counterclaim that Chembio is infringing on SDS's patent, and may have done so willfully. Fletcher v. Atex, Inc., 156 F.R.D. 45, 48 (S.D.N.Y. 1994) ("To assess relevance in a given case, the court must view the matter in light of the specific claims and defenses asserted by the parties.") The documents are relevant in

that they bear upon the nature and extent of relationships between Chembio and third-parties concerning the accused product. Cornell Research Foundation, Inc. v. Hewlett Packard Co., 223 F.R.D. 55, 67-68 (N.D.N.Y. 2003) (granting a motion to compel in a patent case, directing withholding party to produce documents related to any “manufacturing, supply, development, licensing, purchase, research, and collaborative agreement or understanding” between withholding party and third parties, and noting that the sensitivity of the documents would be sufficiently protected by the comprehensive confidentiality agreement in place). See also Moore, U.S.A., Inc. v. The Standard Register Co., No. 98 CV 485, 2000 WL 876884, at * 2 (W.D.N.Y. 2000) (granting a motion to compel in a patent case directing withholding party to produce to moving party’s counsel unredacted versions of requested invoices and purchase orders). In addition, having submitted vendor communications in support of its motion, Chembio cannot now seek to bar inquiry into other vendor communications. Rates Tech. v. Cablevision Systems Corp., No. CV 05-3583, 2006 WL 1026044, at * 1 (E.D.N.Y. 2006) (granting a motion to compel in a patent case, noting that the withholding party raised certain of the requested materials to its benefit, then subsequently sought to bar inquiry into related materials, stating “[s]imply put, [plaintiff] cannot have it both ways.”).

Accordingly, Chembio’s motion for a protective order related to Chembio’s vendor communications is denied. Chembio is directed to produce this discovery pursuant to the terms of the Stipulation and Order governing the exchange of confidential information, signed by both parties and approved by this Court on January 24, 2006.

C. Damages Discovery

SDS seeks discovery related to Chembio's manufacturing costs, vendor communications,

and customer purchases to help SDS assess damages for the alleged patent infringement. (Def.'s Mem. in Opp'n at 11-12.) Chembio argues that this discovery is trade secret information, the disclosure of which will cause irreparable harm to Chembio. (Pl.'s Mem. in Supp. at 18.) The plaintiff cites no case law in support of its position that this sensitive material should not be subject to discovery in a patent infringement case.

35 U.S.C. § 284 provides that in patent infringement cases, courts shall award "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. 35 U.S.C. § 284. To determine a reasonable royalty, courts have taken into consideration, inter alia, the commercial success of the patented invention, the extent to which the infringer has made use of the invention, and the ability of the invention to make money. Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120-1121 (S.D.N.Y. 1970). In order for a claimant to be entitled to damages beyond a reasonable or established royalty, "a claimant must prove his actual damages, that is, his entitlement to lost profits," by establishing that "but for" the infringement, he would have made greater sales, charged higher prices, or incurred lower expenses. Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 671 (Fed. Cir. 1988), cert. denied by Calco, Ltd. v. Water Technologies Corp., 488 U.S. 968, 109 S.Ct. 498, 102 L.Ed.2d 534 (1988). A standard way of proving lost profits is for the patent owner to prove: "(1) demand for the patented product, (2) absence of noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made." State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989).

Accordingly, documents to assist in proving the amount of a reasonable royalty and/or lost profits are discoverable. In particular, defendant SDS is entitled to the discovery sought concerning Chembio's sales and costs (including manufacturing) in order to enable SDS to prove damages. See generally, Stryker Corp. v. Intermedics Orthopedics, Inc., 891 F. Supp. 751, 818-830 (E.D.N.Y. 1995) (setting forth in detail the nature of the documents the defendant produced in order that the Court could determine the amount of damages).

CONCLUSION

Based on the foregoing, SDS's motion to compel is granted, and Chembio's cross motion for a protective order is denied. Chembio is directed to produce the requested discovery, including (1) all FDA files, including trials and evaluations, concerning the Hema Strip and Sure Check HIV products; (2) documents relating to the production of the Hema Strip/Sure Check HIV product; (3) summaries of FDA trials and evaluations and advertising, packaging, etc. for the two products; (4) research and development relating to the Hema Strip/Sure Check HIV product; (5) documents relating to distributors and/or sales representatives for the two products, as well as invoices and customer summaries; and (6) product cost documents.

Defendant's motion for sanctions is denied.

SO ORDERED.

Dated: Central Islip, New York
July 14, 2006

/s/ E. Thomas Boyle
E. THOMAS BOYLE
United States Magistrate Judge